This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21!

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 31-R-0091

CUSTOMER NUMBER: 254

FORM APPROVED
OMB NO. 0579-0036

Ricerca Biosciences Llc
7528 Auburn Road
XXXXXXXXXXXX
Concord, OH 44077

Telephone: (440) -357-3300

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY **(Attach additional sheets if necessary or use APHIS Form 7023A)**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs		1070		13	1083
5. Cats		48			48
6. Guinea Pigs		--			--
7. Hamsters		743			743
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs Mimi		18	34		52
12. Other Farm Animals					
13. Other Animals					
Rats		9763			9763
Mice		6058			6058

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
(b)(6), (b)(7)c		11/26/07

(AUG 91)

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary car programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 31-R-0091

2. Number 1 of animals used in this study.

3. Species (common name) Canine of animals used in this study.

4. Explain the procedure producing pain and/or distress.

   Animals were undergoing GLP toxicology testing. Animal being gavaged struggled and pulled out gavage tube after 2/3 dose administered. When tube was replaced, a gavage error (tube in trachea) occurred and the animal died shortly (15-30 minutes) following dosing. Animal died prior to veterinary examination.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below).

   Animal died before veterinary examination.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   Agency OECD/FDA CFR 409, Title 40CFR

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1. Registration Number: 31-R-0091

2. Number 1 of animals used in this study.

3. Species (common name) Canine of animals used in this study.

4. Explain the procedure producing pain and/or distress.

   Animals were undergoing GLP oral toxicology testing. Animal discontinued eating certified dog chow and refused supplemental can food and water addition to dog chow. Animal unexpectedly found dead in cage.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below).

   Animal died unexpectedly without cause.
   Federally mandated testing in accordance with OECD & FDA guidelines.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   Agency OECD/FDA CFR 409, Title 40 CFR

Column E Explanation

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1. Registration Number: 31-R-0091

2. Number 3 of animals used in this study.

3. Species (common name) Canine of animals used in this study.

4. Explain the procedure producing pain and/or distress.

   Animals were undergoing GLP oral toxicology testing. Animals discontinued eating certified dog chow and required supplemented can food and water addition to dog chow. Approximately 10% body weight lost.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below).

   Other than food supplementation, treatment unauthorized. Toxicity study conducted in accordance with OECD and FDA guidelines. Federally mandated testing.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   Agency OECD/FDA CFR 409, Title 40 CFR

Column E Explanation

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1. Registration Number: 31-R-0091

2. Number 4 of animals used in this study.

3. Species (common name) Canine of animals used in this study.

4. Explain the procedure producing pain and/or distress.

   Animals were undergoing GLP toxicology testing. Top (high) dose of oral toxicity study developed yellow discolor mucus membranes, decreased activity and inappetance. Animals were given a dosing holiday and high dose was reduced to continue study.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below).

   Treatment other than dose reduction unauthorized. Toxicity study conducted in accordance with OECD and FDA guidelines.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   Agency OECD/FDA CFR 409, Title 40 CFR

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary car programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 31-R-0091

2. Number 4 of animals used in this study.

3. Species (common name) Canine of animals used in this study.

4. Explain the procedure producing pain and/or distress.

   Preliminary study using canine to access maximum tolerated dose (MTD) for determining dose levels for repeated and dose toxicity studies. Animals given rising doses until adverse signs (severe vomiting, prostration, poor circulation) are met. Animals are reused for 5-day repeat dose study.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below).

   Treatment unauthorized for reasons below.
   Dose level having adverse effects must be determined to preclude death to animals when administered repeat doses to determine target tissue and toxicokinetic effects of test article.
   Federally mandated guidelines used in testing.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   Agency OECD/FDA CFR 409, Title 40 CFR